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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,838	10/30/2003	Nawaz Ahmad	PPC-834-Cip-5	9254
27777 7590 03/23/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/697,838

Applicant(s)

AHMAD ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: ____                           |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/29/03, 07/16/04, 04/26/04, 10/20/05, 06/20/06, 10/30/06 .

## **DETAILED ACTION**

### ***Summary***

1. Receipt of Information disclosure statements filed on 12/29/03, 07/16/04, 04/26/04, 10/20/05, 06/20/06, 10/30/06 is acknowledged.
2. Claims 1-18 are pending in this application. Claims 1-18 will be examined on the merits.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Borgman (5,840,744).

Borgman discloses a non-flowing (gel) composition having a pH value in the range of about 3.75 to about 4.25, and a method for treatment of bacterial vaginosis by introducing the gel composition into the afflicted area. The composition comprises buffered formulations of a buffer (pH stabilizing agent) and metronidazole, which is 1-(2-

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hydroxyethyl)-2-methyl-5-nitroimidazole, which may be in the form of a clear and opaque gel when anhydrous water soluble solutions form the base of the composition. Borgman teaches that these bases include glycols such as glycerin, polyethylene glycol and polypropylene glycol which are thickened with hydroxypropyl cellulose. See column 9, lines 1-25 and column 10, lines 31-35 and lines 48-52. The examiner is of the position that this anticipates claims 1, 2, 4-9 and 12-18 since metronidazole is an example of an antifungal azole compound, such as an imidazole compound, of claims 1 and 2. Suitable buffers include organic acids such as lactic acid. See column 13, lines 50-56. Claim 10 specifies that the polyethylene glycol is selected from polyethylene glycol 300, polyethylene glycol 400 and mixtures thereof, which is not taught in Borgman. However, Borgman teaches in column 13 that polyethylene glycols having molecular weights in the range of about 100 to about 20,000 may be used which encompasses the claimed compounds. The examiner is of the position that Example 6, compositions I and II, are the closest prior art examples in Borgman and that composition II anticipates claim 11.

5. Claims 1-6, 10, 12-15, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmad et al (5,885,591).

Ahmad et al ["Ahmad"] disclose personal lubricant compositions which comprise at least one water-soluble polyhydric alcohol, a water-soluble polymer derived from cellulose and water. The polyhydric alcohol comprises about 5-90% by weight of the composition and includes glycerin, propylene glycol and/or sorbitol. The cellulose component is

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present in the composition in an amount of 0.01-2% by weight and includes hydroxypropylcellulose. See column 2, lines 1-37. Ahmad allows for the addition of an inorganic base to adjust the pH of the composition to be compatible with the vaginal membranes. See column 2, lines 38-45. Ahmad teaches that the compositions may be used to convey medication or other treatment agents to the biomembranes such as vaginal mucosa. Suitable antifungal agents include imidazole compounds such as miconazole, econazole, and the like. See column 2, lines 57-64. Applicants open-ended claim language "comprising" allows for the addition of other additives to the composition such as water in major amounts. Although treatment of vulvovaginal candidiasis and bacterial vaginosis is not specifically taught by Ahmad, Ahmad teaches that the compositions are suitable in the treatment and prevention of disease in membranes such as the oral, rectal and vaginal mucosa.

6. Claims 1-9, 11, 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (5,002,938).

Wang et al ["Wang"] discloses an antifungal gel composition for topical administration which comprises 0.2-2.0% by weight of an imidazole antifungal agent such as clotrimazole, econazole and sulconazole, and 0.01-2.5% by weight of a 17-ester corticosteroid antiinflammatory agent in a vehicle system comprising (a) a co-solvent system of a lower alkanol in combination with a dihydroxy alcohol or a trihydroxy alcohol, or mixture thereof, and (b) an effective amount to cause gelling of hydroxypropyl cellulose or hydroxyethyl cellulose. Wang teaches that the gel formulation may contain

0 to 20% by weight of water. See column 5, lines 25-38. Glycerin may also be added to the composition. See column 8, line 32. Wang also teaches that the gel has a pH in the range of about 3 to about 5, and that this may be accomplished by the use of conventional pharmaceutically acceptable acids or bases. See column 9, lines 6-15. Applicants open-ended claim language "comprising" allows for the addition of other additives to the composition such as the steroid 17-ester corticosteroid. The examiner is of the position that Wang anticipates the above rejected claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgman (5,840,744) in view of Ahmad et al (5,885,591).

The teachings of Borgman (5,840,744) have been discussed above. Borgman (5,840,744) does not teach the imidazole such as econazole. Ahmad et al. (5,885,591) as discussed above teaches econazole. It would have been obvious to the one of ordinary skill in the art at the time the invention was made to utilize econazole

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in the composition forwarded by Borgman because econazole helps in treating fungal infections. A skilled artisan would thus have been motivated to form a composition comprising econazole with a reasonable expectation of success. A skilled artisan would have been motivated to treat a patient with both nail fungal and bacterial infections with a reasonable expectation of success.

9. Claims 7- 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al (5,885,591) in view of Borgman (5,840,744).

The teachings of Ahmad et al. (5,885,591) and Borgman (5,840,744) have been discussed above. Ahmad et al. (5,885,591) does not teach using alcohols such as lactic acid.

Borgman (5,840,744) teaches lactic acid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize lactic acid in the composition forwarded by Ahmad et al. because lactic acid acts as a buffer and buffers are known in the art to regulate pH. Therefore, a skilled artisan would have been motivated to prepare an antifungal gel composition comprising lactic acid with a reasonable expectation of success.



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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

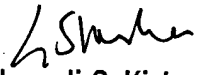
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Group 1600